

Notice of Allowability	Application No.	Applicant(s)	
	09/426,340	SANDAL ET AL.	
	Examiner	Art Unit	
	Diana B. Johannsen	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 11 August 2003.
2. ☒ The allowed claim(s) is/are 1-19 and 21-24.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: _____.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No. _____.
 - (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
 - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1 <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 2 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 4 <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No. <u>0903</u> . |
| 5 <input type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. _____. | 6 <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 7 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9 <input type="checkbox"/> Other |

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Jason I. Garbell on September 3, 2003.

2. **Cancel** claims 25 and 27.

3. **Amend** the claims as follows:

In claim 1, lines 11-12, after "wherein" delete "between step a) and step b)....environmental pool of organisms" and insert therefore—prior to said preparing there is no further purification of the enriched environmental pool of organisms--.

In claim 2, line 2, after "substrate for the" delete "gene product" and insert therefore—polypeptide with an activity of interest--.

In claim 21, line 6, after "harbouring said DNA" insert—sequence--.

In claim 21, lines 10-12, after "wherein" delete "between step a) and step b)....environmental pool of organisms" and insert therefore—prior to said producing there is no further purification of the enriched environmental pool of organisms--.

In claim 21, line 13, after "identify a DNA" insert—sequence--.

In claim 24, line 2, after "encodes" delete "one of".

4. The following is an examiner's statement of reasons for allowance.

The prior art does not teach or suggest methods in which an environmental pool of organisms is cultivated under conditions that result in enrichment of organisms comprising DNA encoding polypeptides of interest, and in which a gene library is prepared directly from the nucleic acids of the resulting enriched pool of organisms without any further purification. Duvick et al (W096/06175 [2/1996])) teach methods of identifying organisms having a particular enzymatic activity (fumonisin degradation) by growing organisms in media in which the enzyme substrate is the sole carbon source (see entire reference, particularly p. 4-6, Example 1). The organisms employed in Duvick et al's methods are obtained from "environmental pools" (e.g., seeds and stalks - see p. 4). However, Duvick et al teach the isolation of organisms that degrade fumonisin prior to library preparation (see, e.g., p. 4, 13, 18, and 24) (see, e.g., p. 24). Accordingly, the claimed method differs from that of Duvick et al, as the methods of the claims are drawn to preparation of a library directly from an enriched pool of organisms, rather than from purified isolates. Further, Duvick et al disclose that newly discovered enzymes are cloned and used in recombinant protein synthesis, as well as transformation of other organisms (see, e.g., pages 6-7). However, while the isolation steps of Duvick et al's method allow identification of the organism of origin for novel polypeptides (and therefore for efficient propagation of the organism encoding the polypeptide of interest, as well as efficient cloning of nucleic acids encoding said polypeptides in a compatible vector and host), the method of the claims results in a library comprising nucleic acids from any type of organism present in the enriched pool

(such that the origin of a nucleic acid encoding a polypeptide of interest is not known). Thus, an ordinary artisan would not have been motivated to have modified the method of Duvick et al so as to have eliminated the step of isolating organisms with the activity of interest. Short et al (US 5,763,239) disclose a method for identifying novel enzymes that comprises preparation of a "normalized" expression library from an environmental sample, exposing the library to a substrate or substrates of interest, and screening the resulting "exposed" library for clones of interest (see entire reference, particularly col 2, lines 11-30). However, Short et al do not disclose a step of cultivating the environmental sample in the substrate (as the instant claims require). In contrast, Short discloses "normalizing" prior to library preparation in order to reduce clone redundancy and increase the representation of rare clones (see, e.g., col 2, lines 25-28); accordingly, Short et al advocate preparing a library in which molecules of all types are equally represented, and therefore teaches away from the claimed invention, in which enriching conditions are employed prior to library preparation in order to produce a library in which molecules having particular activities are present in abundance. It is further noted that the specification teaches that the claimed methods are faster than known methods and allow identification of multiple polypeptide activities and multiple genes encoding polypeptides with the same activity (p. 4), and provides evidence that the claimed method may be used successfully in identifying multiple polypeptides with different activities of interest (see Examples 5-10).

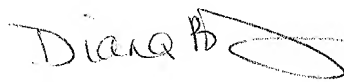
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably

accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 703/305-0761. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on 703/308-1152. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.


Diana B. Johannsen
September 3, 2003


CARLA J. MYERS
PRIMARY EXAMINER